Articles

Decision Making in Critically III Patients With Hematologic Malignancy

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Hematologic neoplasms that were previously considered fatal are now potentially curable with techniques such as bone marrow transplantation. Such therapies also carry significant morbidity and mortality. With the increasing application of these therapies, a growing number of physicians are using medical decision making regarding critical care for these patients. The process by which ethical decisions are reached for these critically ill patients may be baffling because of several factors: rapidly evolving treatments, uncertain probabilities of the cure of the malignant disorder, the relatively young age of many of these patients, and the poor prognosis with critical illness. I discuss a process to reach acceptable decisions, providing a case example of the application of the process. This process is derived from the ethical principles that drive decision making in general medicine and attempts to maximize patients' autonomy. It involves a consideration of accurate information regarding the disease process and the prognosis, a clear delineation of the goals of the medical care, and communication with patients. Appropriate, ethical, and consistent decisions regarding the critical care of patients with hematologic malignancy can be reached when these considerations are addressed.

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Because of advances in treatment, such as marrow transplantation, a growing number of physicians are faced with decisions regarding withholding and withdrawing life support for patients with hematologic malignancy. The treatment of hematologic malignancy poses problems in decision making uniquely distinct from many areas of medicine. These patients are faced with near-certain death without treatment. The treatments themselves, however, are life-threatening while being potentially lifesaving. How far are these treatments to be extended in balancing the possible threat to life with the likelihood of cure? A firm understanding of the decision-making process for critically ill patients is imperative for the rational and consistent care of these patients. In this article I will address the process by which these decisions can be achieved.

The prognosis for patients with hematologic malignancy who become critically ill has historically been poor.²⁻⁴ The dismal prognoses have prompted the recommendation that intensive life support for patients with malignancy is not ethically appropriate: it approaches futility and applies medical resources wastefully. New therapies, such as bone marrow transplantation and biologic response modifiers, offer the possibility of a cure of hematologic neoplasms and other fatal diseases. These patients are often provided heroic levels of care in the hope that life support (including mechanical ventilation) will allow them to survive treatment and return to normal function.

Despite the hopes for cure that attend these treatments, anecdotes suggest that the survival of critically ill patients with hematologic malignancy is infrequent but not unprecedented. Only recently have data regarding the outcomes of marrow transplant recipients been available. These data confirm the anecdotes. Long-term survival for marrow recipients requiring assisted mechanical ventilation is about

5%. Unfortunately, similar data are not available for other recent advances in oncologic therapy. Thus the question arises: on what bases are the decisions to provide (or continue) life support to critically ill patients undergoing treatment for hematologic malignancy made?

Ethical clinical decisions can be reached in these cases if they are made in the context of accepted ethical principles. The decisions are made on the basis of accurate information regarding the disease process and the prognosis, a clear delineation of the goals of the medical care, and input from the patient. Acceptable decisions regarding life-sustaining therapies can be reached when attainable goals and patients' wishes are clearly identified. To this end, accurate information regarding disease processes and prognoses is crucial to establishing realistic goals and informing patients of possible interventions and outcomes.

Goals of Medical Care in Oncology

The goals of care in patients with hematologic malignancy should be common to those of medicine in general. The goals of medicine in the Western culture were expressed early in medical literature and, as stated in the Hippocratic Corpus, are the attenuation of disease, the relief of suffering, and restraint from the treatment of hopelessly ill patients (lest physicians be thought of as charlatans).⁷

Throughout most of history, there was little that medicine could offer to alter the outcome of disease. The principal endeavors of medicine were to provide diagnoses, prognoses, and supportive care. Modern advances in anesthesia, surgical technique, antisepsis, antibiotics, and vaccines have changed the capabilities of medicine, and modern society has altered its expectations. Because medical technology now permits us to alter disease processes, Western society has imposed additional goals on medical providers. The attenua-

tion of disease and relief of suffering, while still important endeavors, are now joined (or supplanted) by the goals of maintaining or restoring function and prolonging life.8

These notions that medicine can "save life" and "cure disease" are recent in human history and a reflection of scientific advances. Immunology and transplant biology represent novel extensions of our newly discovered capacities to affect the outcome of disease. Thus, while Hippocratic goals are still relevant, it is increasingly difficult to apply the last of the Hippocratic injunctions, namely, to refrain from treating hopeless cases. The question today is, what case is hopeless? For example, should the promise of cure with a successful marrow transplantation impart hope to otherwise desperate cases?

Pertinent to this example, most candidates for marrow transplantation suffer from ultimately fatal diseases. On the whole, these patients are rarely older than 50 years. For them, the goal of intervention is to cure disease, leading to the restoration of normal function and life expectancy. At the very least, it is to prolong life. These patients choose this mode of therapy with the expectation of cure. The same is true for patients receiving other novel therapies for the treatment of hematologic malignancy.

The limitations of new therapies are not known. Clearly, not all patients can or will be saved by these technologies. Experience to date is limited in both numbers of disease processes and patients treated. The patients who will not survive grave illness during treatment are difficult to identify with certainty. Therapies to treat both the malignant disorders and the complications of the treatments are evolving rapidly. New discoveries may favorably influence the prognosis of critically ill patients with hematologic malignancy. An example of a dramatic improvement in the prognosis of a serious infection is the successful treatment of cytomegalovirus pneumonia after marrow transplantation with the newly developed antiviral agent ganciclovir. 10.11

Given the problems posed by the relative lack of experience with specific treatment modalities for hematologic malignancy and the rapid advances in treatment-related complications, how can reproducible solutions be found for the ethical dilemmas of the care of the critically ill? Because the goals of medicine apply to patients with hematologic malignancy, it is reasonable to assume that the principles of decision making that apply to medicine in general can be adapted to the setting of advanced oncology treatment.

Considerations for Clinical Decision Making

The process of medical decision making should adhere to accepted ethical principles of the society in which the medical care is provided. Webster's New World Dictionary defines "ethics" as the system or code of morals of a particular philosopher, religion, or group. Thus, ethical principles are the tenets that describe what is "right" or correct behavior within a society. While each of us has an internal code of morality, a personal ethic, it is physicians' responsibility to practice medicine within the morality of the society. The fundamental principles of medical ethics in Western society have been summarized in the ideals of beneficence, autonomy, and justice. These ideals serve to protect and guarantee the rights and interests of the individual within the context of the needs of the society.

Beneficence is the principle that medical intervention should be in the best interest of the patient. Autonomy indicates that individual preferences are given high regard in decision making and that competent patients may refuse intervention. The intervention should be equitable and just, thus serving the greater interests of society.

Patients with fatal hematologic malignancy present distinct problems to the considerations of withdrawing and withholding life support. First is the relatively young age of many of these patients and the potential to return to a normal life span and function with successful treatment. Second is the potential for a significant risk of toxicity or premature death due to the treatment. Third is uncertainty regarding the probability of successful treatment or of the level of risk for an unfavorable outcome in the event of complications. These problems increase the difficulty in dealing with these patients and make it imperative that the basic ethical principles be followed in decision making.

Presentation of a Case

The patient, a 27-year-old married man, underwent allogeneic marrow transplantation for acute nonlymphoblastic leukemia in relapse. The sibling donor was mismatched with the recipient at one HLA locus. The patient was seropositive for cytomegalovirus (CMV).

He was conditioned for transplant with high-dose cyclophosphamide therapy and fractionated total body irradiation. By day 40 after transplantation, the donor marrow had engrafted with a circulating absolute neutrophil count above 1.0×10^9 per liter (1,000 per μ l), but persistent thrombocytopenia necessitated frequent platelet transfusions. Early evidence of hepatic veno-occlusive disease and mild renal dysfunction was abating, and oral mucositis had resolved. A skin rash and elevated serum aminotransferase and bilirubin levels were felt to represent acute graft-versus-host disease. There was no evidence of residual leukemia.

Respiratory distress then developed, and bilateral pulmonary infiltrates were seen on a chest film. He requested, "Help me, I can't get my breath." Assisted mechanical ventilation appeared necessary as life support on the basis of his respiratory status. At this point, the patient's wife said, "I don't want him to live the rest of his life on a respirator." What were the appropriate medical decisions?

The Process of Decision Making

Defining the Goals

The pivotal point for the process of medical decision making is identifying the goal of intervention. The definition of an appropriate goal is paramount, particularly when considering the indications for proposed medical intervention. An "appropriate" goal is both consistent with the patient's aspirations and capable of being achieved. Who chooses the goal that defines the indications for treatment?

In its report on informed consent, the President's Commission for the Study of Ethical Problems concluded that the decisions about health care ultimately rest with the competent patient. ¹² Therefore, all questions regarding medical decision making must be framed within the context of a patient's intent. Adult patients have the right to refuse treatment, regardless of the benevolent intent of their physicians. The physicians' recommendations for treatment, however, are made on the basis of an understanding of the goals desired by the patient. Patients' acceptance or refusal is made on the basis of the perceived burdens and risks of the intervention relative to the possible benefits.

Autonomy, or self-determination, is a crucial element in medical decision making in our society. United States court decisions have affirmed competent patients' right to refuse medical interventions. To be able to consider medical care, however, patients must weigh the options available in relation to the goals they wish to achieve. Thus, all consideration of potentially expensive, intensive, lengthy, and painful life-sustaining modalities must include the concept of "proportional treatment." Is there "in the view of the patient, . . . at least a reasonable chance of providing benefits . . . which outweigh the burdens attendant to the treatment"? This question applies to patients with hematologic malignancy as well. What potential pain or inconvenience is appropriate for a patient to endure for the unknown chance of survival? What level of benefit warrants the sacrifice?

Central to the concept of proportionate treatment is the phrase "in the view of the patient." This concept requires that physicians provide patients with information regarding the anticipated risks associated with each treatment course and the probability of outcomes, so that patients may determine their preference. Physicians, as medical experts, have a responsibility to counsel patients regarding a course of treatment and to explain the attendant risks and benefits, as well as alternatives to the recommended course. Adult patients' preferences, informed by physicians' recommendations, are foremost in deciding the ultimate balance of proportionate treatment.

The initial task of a medical provider is to delineate clearly the goals of a patient so that appropriate interventions may be offered. The subsequent tasks are to inform the patient as to the probability of achieving the goal and the likely clinical course that will ensue. It would be useless to propose interventions that offer no probability of securing the patient's goal. It is the responsibility of physicians to avoid such counsel and inform patients when the goals cannot be met. On the basis of the information, a patient can agree or refuse intervention. In the oncology unit, the difficulty in this task is compounded by the lack of data regarding risks, burdens, and probability of benefit for many interventions. Without such information, a truly informed decision by a competent patient is impossible.

The patient in the example was at high risk for CMV pneumonia, and the presentation was consistent with that diagnosis. Although the mortality of this condition had been over 85%, treatment regimens with ganciclovir and immune globulins have reduced it to as low as 30%. ^{10,11} Respiratory failure, apparently independent of cause, may be a grimmer prognostic factor for marrow recipients. The chance of surviving beyond six months after assisted mechanical ventilation appears to be only 5%. ⁴ Patient characteristics and associated organ failures do not appear to be predictive of survival. Anecdotally, some marrow recipients with multiple organ failures have been long-term, disease-free survivors after receiving mechanical ventilatory support.

This man opted for the transplant with the fervent hope and expectation of a cure of his malignant disorder and a return to a functional life. He undertook the transplant with the understanding that the probability of disease-free survival was less than 20% given his disease status. His goal of treatment at this point remained unchanged from before: to cure the malignant disorder. Because potentially effective therapies existed for the most likely disease that this patient had

(CMV pneumonia), this was an appropriate and achievable goal.

Medical Indications for Treatment

It has been argued that there is no imperative to provide futile medical intervention. 14 In fact, it may be appropriate to withhold interventions that are futile. The problem lies in deciding which interventions are futile. Schneiderman and co-workers have proposed that futile interventions be described as "any effort to achieve a result that is possible but that reasoning or experience suggests is highly improbable and that cannot be systematically produced." To give this description quantitative value, they suggested that an intervention be considered futile if, on the basis of studies or experience, success is not achieved in 100 attempts. This description of futility provides little help to the consideration of critically ill patients with hematologic malignancy. For many of these patients, there is insufficient information on which to conclude that the rate of success is less than 1 in 100. The interventions often are too novel and the clinical situations too complex to compile a sufficient number of reference cases. Extrapolating from other disease states may not be possible given the novel treatments often used. Schneiderman and associates recognized that rare disorders may present with "insufficient experience for a confident judgment of futility."15(p952) In such cases, they suggest that "In judging futility, as in other matters, physicians should admit uncertainty rather than impose unsubstantiated claims of certainty."

I agree with these points, but the admission of uncertainty in these cases includes admitting ignorance regarding the certainty of the futility or of the success of the intervention. It is true that medical progress is not made through repeated futile intervention, as Schneiderman and colleagues noted. In addition, progress is not made through the assumption of the futility of interventions for which insufficient experience exists. Thus, interventions should rarely be withheld solely on the basis of supposed medical futility when the intervention is either novel or experimental. This is not to deny that there may be other valid reasons for either not offering novel intervention, or for the patient not accepting it, regardless of the probability of benefit.

This lack of appropriate information regarding the prognosis and likely course of the disease in the setting of advanced treatment of hematologic malignancy is the greatest hurdle to decision making. Often the basis for medical recommendations becomes anecdotal evidence. Thus, the interventions become truly empiric—not based on scientific theory but on personal experience and bias of therapeutic value. Because there is a lack of information, oncologists should request and rely extensively on the experience and expertise of other medical specialists.

The medical indications for intervention in this case clearly depended on an accurate diagnosis of the patient's condition and a prognosis based on the best current data about the natural course of the disease and the treatment options. Confirming a definitive diagnosis was in this patient's best interest. Diagnostic efforts such as bronchoscopy with bronchoalveolar lavage were indicated.¹⁶

Survival from respiratory failure, should it ensue, would not be unprecedented, but it would be unlikely. Thus, it was possible but improbable. Experience at many marrow transplant centers suggested that the probability of successfully treating CMV pneumonia complicated by respiratory failure was low. Since the demonstration of the beneficial effect of current therapy on the outcome of CMV pneumonia, there is reason to think that the probability of recovery from this condition is now improved. It must be admitted, however, that too little experience exists to be certain that the therapy increases the incidence of successful outcomes in the presence of established respiratory failure. It would be difficult to describe recovery as "highly" improbable or less than 1 in 100, as Schneiderman and co-workers suggest as a threshold to indicate medical futility. At this point in the patient's illness, it was not clear that the patient's goal was unattainable.

If this patient had not undergone marrow transplantation, these levels of probability would constitute futile intervention because any clinical success would be at best temporary: the patient's underlying disease would wipe out any immediate gains, and his death would be imminent. For this patient, who had received a transplant that had the potential of preserving life for a considerable period if he survived this crisis, the low (but unknown) probabilities should not be considered indicative of futility. Therefore, from the viewpoint of medical indications, critical care, including a trial period of mechanical ventilation, would be justified.

A consideration of justice plays a limited role in clinical decision making for critically ill patients with hematologic malignancy. Decisions regarding the just macroallocation of resources are not made at the individual patient level. We practice medicine within the constraints of the resources allotted by society. The microallocation of resources, however, profoundly influences decision making at the individual level. The inability to pay for potential therapy and the possibility of financial destitution of a family after expensive treatment are considerations. These "microjustice" concerns and the implication for patients and their families are best understood and decided by them, not their physicians. For these reasons, the concept of justice should be superseded by patients' autonomy in most decisions of withholding or withdrawing life support.

Patients' Preferences

In the case presented, the patient must determine the "proportion" of burden and benefit in his situation. He could not do this in a vacuum of medical information and relied on his physicians for counsel and advice. 17.18

The patient had never explicitly discussed with his physicians his desires regarding terminating therapy. At this time he was critically ill, sedated, and depressed because of the length of his hospital stay. His mental state raised doubts regarding his capacity to participate in the decision about continued medical care and the possible requirement for ventilatory support. In the absence of direction to the contrary, it was prudent to assume on the basis of the patient's participation in the transplant program that he valued life. Medical interventions and life support were provided in an attempt to achieve the goal of curing his disease as long as it was a medical possibility. Discussion with the patient about these decisions would have been appropriate after the institution of this medical support had he recovered his ability to participate.

Experience with the acquired immunodeficiency syndrome suggests that patients want to be actively involved in

decisions regarding their care.¹⁹ Patients confronted with the prospects of mechanical ventilation for *Pneumocystis carinii* pneumonia are capable of choosing to forego this intervention.²⁰ In addition, patients not approached often express a wish to discuss these options with their physicians. Perhaps oncologists should routinely and explicitly discuss intensive care and mechanical ventilation with patients and families before marrow transplantation to determine patients' preferences.

Use of a Surrogate

Medical decision making for physicians is particularly difficult when a patient is mentally incapacitated. The use of an appropriate surrogate (usually the next of kin or a legally designated party) to speak for (and in the best interests of) an incapacitated patient facilitates the decision-making process but also poses difficulties. Among these, the patient must clearly be shown to be incapable of understanding the data presented and expressing his or her wishes before the autonomy of the patient is bypassed. ¹² Just as a patient is assumed to opt for potentially life-saving intervention over death, the patient is assumed to be competent to participate in decision making over involving a surrogate.

The patient presented could participate in the decision-making process to the extent that he said that he was short of breath and wanted relief of this sensation. Beyond these comments, the consensus of medical opinion (including consultation with psychologists) was that he could not adequately process information and arrive at cogent decisions because of the severity of his illness. In this situation, his wife was most appropriate to act as his surrogate as she was most likely to understand his motivations and anticipate his decisions. As well, she would most likely present decisions from a position of intimate and loving concern for his well-being.

Her responsibility was not to make decisions for her husband but to relay the decisions that he would have made if capable. The goals of therapy desired by the patient should direct care, provided the goals (such as cure of disease) were attainable. To this end, both the medical staff and family would have benefited from any previously expressed wishes for his care. If his wife had not known what choices he would have made, she could assist in making decisions that would serve his best interest.

The potential uncertainty of decisions and the emotional trauma to his wife in acting as a surrogate might have been avoided had the patient provided advance directives before his critical illness about the desirability of life support. In addition, the patient could have appointed another surrogate (or durable power of attorney for medical care) to make crucial decisions in his behalf.²¹ Preparations like these are more likely to occur if physicians anticipate the likely medical course and discuss the possible choices for each complication in advance.²¹

Because the determination of medical facts and the interpretation of the preferences of patients and surrogates in this case were difficult, the use of an institutional ethics committee could have been helpful. These committees, now common in United States health care, do not usurp the role of attending physicians or of the patients and families.²² These parties retain the authority to make decisions. The opportunity to discuss the medical complexities, the ethical principles, and legal implications of these decisions, however, can

be enhanced by presenting them to a knowledgeable and impartial group. The deliberations of such committees can assist the primary decision makers in seeing what is often difficult to see when closely involved in a case.

Quality of Life

The statement, "I don't want him to live the rest of his life on a respirator," by the wife of this patient likely reflected concern about his potential suffering. The exact meaning of her remark was not clear, however. Such comments by family members are unfortunately common, but whether they reflect concern for possible short-term suffering, long-term disability, or "death with dignity" issues is often vague. More important, it is not clear whether such statements reflect views and wishes of the patient or of the family.

Statements such as the one quoted should prompt frank discussion between the physician and the patient and family. The true concerns should be spelled out clearly and information regarding the possible outcomes from treatments detailed. The relative value of life (including life with disability) and the degree of discomfort or suffering a patient is willing to accept to attain that life must be explored before decisions regarding care can be reached.

There is no reason to suspect that marrow recipients who survive respiratory failure have long-term ventilatory impairment. Anecdotal experience suggests that such patients have a gradual return to normal function analogous to that seen after the adult respiratory distress syndrome in nonimmuno-suppressed patients.²³ Given his respiratory failure and a lack of direction from the patient otherwise, it was appropriate to discuss the prognosis and course with the patient and his wife to allay their concerns. A therapeutic trial of ventilatory support was appropriate to permit time for diagnostic procedures to be completed. In addition, more information regarding the extent and course of his disease would become available during this trial period.

His wife concurred that such an approach was consistent with the patient's desire for cure and would be in his best interest. Assisted mechanical ventilation was instituted and bronchoalveolar lavage done. The viral immunofluorescent antibody stains and cultures were positive for CMV. Treatment with ganciclovir and CMV-specific immune globulin was begun.

Inability to Achieve the Goal

As discussed, there were few data to indicate the prognosis of respiratory failure due to CMV treated with ganciclovir. Thus, it was difficult to define if or when this would constitute futile intervention. There was an appropriate sense of urgency to arrive at a decision regarding treatment because the emotional and financial implications were substantial. Given the difficulties, it was important that the primary oncology team work closely with consulting physicians to reach a consensus regarding prognosis and treatment. A reasonable approach was the institution of a time-limited therapeutic trial of assisted mechanical ventilation and specific CMV treatment. If, in the best judgment of medical experts, reasoning and experience would suggest that treatment would have no chance of curing the disease (or the patient decided that the likely outcomes of treatment did not justify the burdens posed on him), it is reasonable that the goals of treatment must change. Such a consensus would have been

reached in this case if fulminant hepatic failure, progressive respiratory compromise refractory to maximal oxygenation support, or a relapse of his leukemia were to ensue or no clinical improvement were noted after a reasonable, predetermined period of time.

Data in many subsets of critically ill patients suggest that the survival rates for such complications are less than 1%. At that point, reasonable goals would become the relief of suffering and providing suitable time for the patient and family to attend to necessary arrangements in the anticipation of death. With these goals in mind, the continuation or institution of new technologies that did not relieve suffering would be inappropriate. The new goals would dictate that comfort measures be instituted and that interventions not contributing to these ends be terminated.

The sequence of the withdrawal of support and the level of sedation and analgesia that are required vary in each case, but the goals of the actions should be clear to all involved.¹⁷ To this end, imposing or continuing support with arbitrary limitations, such as limiting oxygen concentrations or continuing vasopressors or antibiotics at preset rates of administration, do not achieve any goals. Such actions give the appearance of medical care but are not expected either to cure the patient or to relieve suffering and do not prolong life. The continuation of "limited" medical care is contrary to the assurance of a quality life and death in many cases, unless there is another goal that will be achieved by the action. Occasionally care is continued until the patient or family has achieved a short-term goal, such as the arrival of a relative who wishes to be present.

In the case of the marrow recipient presented, pulmonary function and gas exchange continued to decline steadily over a ten-day period despite evidence of the eradication of the CMV infection. Arterial hypoxemia and increasing minute ventilation requirements necessitated 100% supplemental oxygen, high levels of positive end-expiratory pressure, and increasing respiratory rates that were inadequate to achieve physiologic blood gas values. When declining renal function ensued and hemodialysis became necessary for continued survival, a consensus of medical opinion was sought among the transplant team, pulmonary and critical care physicians, and the nephrology consultants. The conclusion was reached that there were insufficient data to state conclusively that there was no probability of survival, but the steadily declining course despite near-maximal life support made recovery highly improbable. On the basis of collective experience, it was concluded that the probable course would include continued mechanical ventilation, hemodialysis, recurrent pulmonary infections, and other complications.

Because the patient still could not participate in decision making, his wife continued to act in his best interest as surrogate. She was told of the collective medical evaluation. In light of the consensus that the goal of cure would not be reached, the alternative goal of a quiet and orderly death was recommended. At this time, she agreed that her husband would not have opted for the prolonged life support with such limited probability of survival. At that point, adequate sedation was administered to relieve any discomfort, and interventions not necessary for comfort were withdrawn. These included hemodialysis, antibiotics, blood products, and supplemental oxygen. He died quietly in the company of his immediate family.

Conclusions

This case demonstrates several important aspects of the process of decision making in cases of critically ill adult patients undergoing therapy for hematologic malignancy:

- The goals of medical care should be clearly defined before the implementation or withdrawal of treatment.
- Informed decisions regarding treatment should be made by the patient with the assistance of medical staff. Whenever possible, patients' preferences regarding life support and quality of life should be solicited before medical intervention, especially when the likelihood of the patient being incapacitated during the procedure is high.
- Physicians must possess accurate information about the prognosis, risks, and benefits of available treatments. To this end, a consensus of expert medical opinions is advisable before reaching conclusions regarding prognosis. Continued studies and the publication of critical care treatments are necessary in specific patient populations to accurately determine prognoses.
- Surrogates should not be asked to make decisions in the place of an incapacitated patient but rather to make substituted judgments, that is, to determine the patient's preferences. Patients' preferences are paramount; family wishes are not.

In addition, the process of making acceptable and ethical choices in such cases is difficult and emotionally draining for physicians as well as patients and families involved. The care of patients may benefit by the formation of an ethics committee to discuss those cases that possibly involve issues of withdrawing or withholding life support.

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